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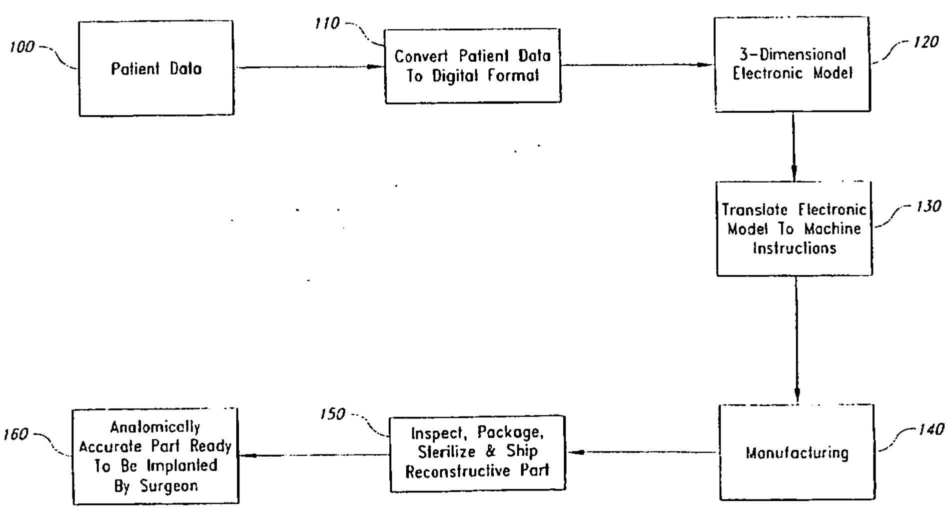
(54) Title: SYSTEM AND METHOD FOR RAPIDLY CUSTOMIZING A DESIGN AND REMOTELY MANUFACTURING BIOMEDICAL DEVICES USING A COMPUTER SYSTEM



(57) Abstract: A method of rapid design and manufacture of biomedical devices using electronic data and modeling transmissions, wherein such transmissions are transferred via a computer network. The method includes capturing patient-specific diagnostic imaged data, converting the data to a digital computer file, transmitting the converted data via the computer network to a remote manufacturing site, converting the computer file into a multi-dimensional model and then into machine instructions, and constructing the biomedical implant. The present invention is further directed to the preparation of rapid-prototyped pharmaceutical forms, including oral dosage pills and implantable pharmaceuticals, with transmittal of such data over computer networks being used to significantly increase the cost effectiveness and responsiveness, and is further directed to the use of a website to perform various client-interaction and follow-up tasks.

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SYSTEM AND METHOD FOR RAPIDLY CUSTOMIZING A DESIGN AND REMOTELY MANUFACTURING BIOMEDICAL DEVICES USING A COMPUTER SYSTEM

TECHNICAL FIELD

The present invention relates generally to manufacture of biomedical devices, and more particularly, a novel method and system for rapid customized design and manufacture of biomedical implants using a computer system and transmitting data over globally based information networks such as the Internet.

BACKGROUND OF THE INVENTION

The World Wide Web ("the Web") is an interactive computer environment. The Web uses a collection of common protocols and file formats, including the Hypertext Transfer Protocol ("HTTP"), Hypertext Markup Language ("HTML"), SOAP (Simple Object Access Protocol), and XML (eXtensible Markup Language), to enable users to obtain information from or exchange information with a huge number of organizations, via the Internet, from virtually anywhere in the world. In order to establish a presence on the Web, organizations generally construct a "Web site." Such a web site generally includes a collection of documents relating to the organization that is accessible by users using an address on the Web, called a Universal Resource Locator ("URL"), publicized by the organization.

The Web is increasingly used as a channel for transmitting information as well as for commercial activity. Many organizations have achieved great success at selling products and services through their web sites. For instance, a significant fraction of the airline tickets, music compact discs, and books sold today are sold via the Web.

In the medical field, the Internet and similar computer networks have proven to be useful for transmitting information for medical applications. The general term "telemedicine" refers to this practice. Telemedicine includes transmitting simple data, remotely monitoring patients' conditions, transmitting visual and pictorial

such as visualization, surgical practice, surgical planning, and design of templates. Various devices made by three-dimensional printing methods were disclosed in U.S. Patent No. 5,490,962. The devices were of a standard geometry. The patent did not disclose machine instructions or a procedure for converting an individual's unique radiographic data into machine instructions. Further, the prior art does not provide a method for providing a rapidly manufactured customized implant, nor does it disclose the use of the Internet in transmitting such information among sites.

SUMMARY OF THE INVENTION

The present invention provides a new method and system of rapid design and manufacture of biomedical devices using electronic data and modeling transmissions, wherein such transmissions are transferred via computer networks such as the Internet. The method includes capturing patient-specific anatomical data, converting the data to a transmittable form, transmitting the converted data to a remote site, converting the computer file into manufacturing instructions, and manufacturing the biomedical device such as an implant, preferably by rapid manufacturing methods which are suitable for medical use, and delivering it to the doctor/patient. The method may further include converting the computer file into a multi-dimensional geometric model. One example of a biomedical implant is an implantable reconstructive, augmentative, rehabilitative or cosmetic device, such as bone. One method for rapid construction of reconstructive, augmentative, rehabilitative or cosmetic devices is three dimensional printing, which involves selectively bonding together powder in successively deposited layers. Such technology allows implants to be manufactured with a great degree of design freedom and complexity as far as dimensional design, and also as far as material composition, porosity, internal architecture, and the like. In particular, it is possible to design active content into the architecture of the implant, such as drugs, DNA, growth factors, comb polymers, and the like, that can direct, promote, or discourage ingrowth of bone, soft tissues, or vascularized tissue in particular places.

planning process as well as allowing custom manufacturing of the implant. Within the context of the present invention, data transmission implemented over a globally-based information network, such as the Internet supporting the World Wide Web, facilitates the design of an implant customized for a particular patient, allows one to visualize and confirm its suitability, and allows manufacture and delivery of the anatomically accurate implant to the doctor, all within a few days, which is much faster than presently possible. This would greatly increase the responsiveness of the medical system, with attendant benefits to patient treatment, especially in emergency treatment. It would also reduce geographical restrictions on the availability of this medical technology.

The present invention provides a new method of rapid design and manufacture of biomedical implants using electronic data and modeling transmissions, wherein such transmissions are transferred via a computer network such as the Internet. The method includes the steps of capturing patient anatomical data, converting the data to a computer file, transmitting the converted data to a remote site, converting the computer file into a multi-dimensional model and then into machine instructions, and finally manufacturing the medical device such as an implant. One example of a biomedical implant is an implantable reconstructive, augmentative, rehabilitative or cosmetic device, such as bone. Another example is a custom designed pharmaceutical such as a surgical leave behind or a custom dosage pharmaceutical. Yet another example is cartilage implants or soft tissue implants.

Figure 1 is a flow diagram showing steps of the method in accordance with one embodiment of the present invention. Patient-specific data is 100 provided by the attending physician regarding the surgical or reconstruction site. This patient data 100 is converted into a digital format 110 and saved into a computer hard drive, floppy disk, compact disk, or other form of data storage. In one embodiment, after transmission of this data, a multi-dimensional model 120 is constructed from the transmitted data. Machine instructions 130 can be translated from either the multi-dimensional model 120 or from the data in digital form to facilitate an automated manufacturing 140 of the medical device such as an implant. Upon completion of the customized device or

to the maintenance and transfer of individuals' medical data. Accordingly, it would be advantageous to encrypt the data before transmission and to decrypt the data after transmission, as is known in the art. Alternately, data could also be transmitted, for example, by storing the data on a data storage device such as a floppy disc, compact disc, DVD disc, optical disc, magneto-optic disc, WORM (write once read many times) disc, and sending the storage device via traditional mail services. In the event that the manufacturing site coincides with the location of the patient the doctor and the diagnostic equipment, data transmission via the Internet may not be necessary.

Patient data from, for example, MRI or CT scans is normally presented as sets of two-dimensional images (sections) showing all of the patient's tissues. The slices in a CT scan or an MRI scan associate, with each coordinate location in a scan, an intensity of brightness on the display. In the case of a CT scan, darkness corresponds to absorption of X-rays that is most closely correlated with density of the tissue. In an MRI scan, intensity refers to the presence of certain elements. CT scans are considered better for imaging hard tissue such as bone, and MRI scans are considered better for imaging soft tissue. There may be instances in which it is advantageous to use both types of imaging together with each other.

In some instances, for example, an implant that joins to existing bone, the diagnostic scans may need further processing. Further processing may include, for example, more clearly distinguishing between hard and soft tissue, as well as defining solid boundaries or surfaces of the hard tissue, for example, bone, in the two-dimensional planes or sections in which the MRI or CT scans typically are presented. Identifying the edges or surfaces of bone can be achieved by appropriate sampling and threshold definition techniques (perhaps including contrast enhancement) and geometrical algorithms such as in the software package MIMICS (from Materialise Europe; Ann Arbor, MI). This initially processed data may further be converted to a form that geometrically represents a multi-dimensional form representing an object. Such mathematical representations typically feature curved surfaces with resolution available to almost any desired precision anywhere on the surface, not only at locations which were part of the scan planes of the original MRI or CT data, but also in general at

dimensional model is SolidWorks (SolidWorks, Concord MA). Another is ProEngineer (Parametric Technologies, Waltham, MA).

In accordance with another embodiment, data is combined from more than one type of scan, such as MRI and CT. In combining two different scans typically taken with two different sets of equipment and two different positionings of the patient, one challenge is to determine the appropriate relative position and orientation of the models obtained from the two methods. For example, CAD software is usually capable of calculating the centroid of a solid object. Aligning centroids of objects resulting from different types of scans is one way of comparing them. Alternatively, or in conjunction with aligning the centroids, the parts could be aligned as far as angular orientation. Further criterion such as mathematically subtracting one model from the other, for example, by a Boolean operation, a set of space representing points is obtained which are members of one model or the other model but not both. The volume of this could be calculated, for example, by CAD software. When the volume of this spatial difference is minimized, the best alignment of the two parts has been achieved. After the best alignment of the two versions of the bone is determined, a combination or average of the two scan results could be calculated and used for the best representation of the bone surfaces.

The multi-dimensional model created so far from diagnostic data is a model of existing bone structure in a patient's body. As a first step in creating a model of the object to be manufactured, a decision must be made as to whether the part which is to be manufactured corresponds to solid regions displayed in a diagnostic scan (*i.e.*, if the part is a replacement part), or if it corresponds to voids displayed in a diagnostic scan (*i.e.*, if it is a filler piece). If the part is a replacement part, it is possible that all of its edges are defined by edges of existing bone that is already represented by the multi-dimensional model. If it is a filler piece, some of its edges can be mathematically defined by Boolean operations in the CAD program where the part adjoins pieces that are already defined as solid (*e.g.*, existing bones). Where the new part adjoins soft tissue, edges may have to be defined by the software operator. Movement to remove or

Yet another geometric modification could be changing the model, for example, enlarging the entire part by a predetermined factor in all or certain directions to compensate for anticipated shrinkage during post-manufacturing processing steps. Such shrinkage is known in the art, along with how to compensate for it.

The software and computer facilities needed for this stage of the process may typically be sufficiently sophisticated, expensive or specialized that they would be unavailable at an individual doctor's office but one advantage of use of the Internet is that such facilities would be easily available at central site after transmission of the raw data out of an individual doctor's office. The multi-dimensional model may be stored, processed and transmitted in the form of an IGES, STEP or similar file, as previously described.

Beyond geometric alteration, there is also another possible step of the process of designing an implant. This step would require associating a composition variable or an internal architecture with specific geometric locations in the multi-dimensional model. Composition variation can be implemented in three-dimensional printing most clearly by dispensing various different binder liquids from different nozzles, with coordination of the nozzles so that their relative target points are known. Additionally, specific chemicals in predetermined locations may be seeded into the implant during manufacturing. For example, growth factors, DNA, etc. can encourage ingrowth of bodily tissue such as bone at designated places. Comb polymers can encourage or discourage various types of cells from locating in designated places, as can modifiers of surface hydrophobicity. Porosity of the final product can also be designed in as a variable. Depending on the desired size scale of porosity, it can be designed into the architecture or can be achieved by manufacturing details, as is known in the art. Color, including variations of color, could also be designed in if desired. It would be possible to put in marker substances that show up on MRI or other forms of radiography, so that the part can be better inspected later. For example, two or more markers could be designed in to the part at a known distance apart from each other. Depending on the modeling software, it may be possible to associate these details with the multi-dimensional model at

In one embodiment, the designed multi-dimensional model data is transmitted back to the doctor/patient for their review. Multiple review iterations may be performed as changes are discussed and agreement is reached with the doctor/patient. A system that is implemented in hardware could allow a substantial number of design iterations in a short period of time particularly if it operates in near real time. Further, such a system could provide the medical field a capability of concurrent design or collaborative or interactive design. The final multi-dimensional model file can be transmitted over the Internet to the manufacturing machine if that machine is located at still another location. Thus, the computer facilities and software that process the radiological data to form the multi-dimensional model do not have to be co-located with the manufacturing facility.

In yet another embodiment, various details are transmitted back to the client or doctor for viewing along with the multi-dimensional model. If the transmittal of proposed designs from the remote location back to the doctor is done by files such as IGES or STEP, it will be possible to transmit as much geometric detail as desired, but it may not be possible to transmit much compositional detail such as distributions of color on the surface, or other compositional variation such as placement of bioactive substances. IGES would be more limiting than STEP in this respect. If the transmission of data is done with proprietary file formats tied to the software of a particular CAD software vendor, it may require that the doctor/patient location use the same software for viewing the image of the proposed part. For transmission of the multi-dimensional model back to the doctor/patient for viewing, it is not necessary for the doctor/patient to have a complete license to the CAD software which was used in making the patient-unique multi-dimensional model; many software packages nowadays are offer simplified versions whose only capability is to open and display files generated by that program, without actually being able to modify them. Alternatively, the computer terminal at the doctor/patient could simply be configured as a remote user of the software that is installed at the central computer.

Encryption would be desirable in any such data transmission. Transmission of approval from the doctor to the manufacturer can be stored with the

instructions representing the part geometry at that particular plane. In three-dimensional printing, each slice corresponds to a layer of powder in the powder bed during construction of the object. The entire set of data or instructions is referred to as the machine instructions.

In a general sense, the slices which are the manufacturing instructions bear a general resemblance to the scan planes which make up an MRI scan or CT scan, but there are important differences. The slices in an MRI or CT scan are acquired diagnostic data. The slices that are manufacturing instructions are processed data containing additional information. The slices that are the manufacturing instructions are typically spaced at the layer thickness of powder spreading, rather than at the scan planes interval of MRI or CT. Quite possibly, the powder layer spacing interval is much smaller than the scan plane interval of the MRI or CT.

Additionally, the angular orientation at which the manufacturing slices are taken does not need to have any particular orientation with respect to the angular orientation of the scan planes of MRI or CT. The scan planes are for convenience of diagnostic imaging, and the manufacturing slices are for convenience of manufacturing.

The slices in a CT scan or an MRI scan associate with each coordinate location in a scan and an intensity of brightness on the display. In the case of a CT scan, darkness corresponds to absorption of X-rays that is most closely correlated with density of the tissue. In an MRI scan, intensity refers to the presence of certain chemical elements. Both of these types of quantities can have a whole range of values (*i.e.*, analog). In contrast, the print instructions for any given coordinate location are in many cases essentially digital, instructing particular dispensers to either dispense or not dispense.

Generating the machine instructions includes mathematically taking a cross-section of the multi-dimensional model at locations corresponding to the layers of the three-dimensional printing process. The machine instructions describe the entire interior solid structure of the manufactured part, whereas the multi-dimensional model merely describes the surface.

In such a case, additional information would have to be associated with each print command in the machine instruction file.

Thus, in addition to the geometric data, the machine instruction file also contains compositional information relating to the situation where more than one binder substance is dispensed onto the powder.

The method just described provides a method of manufacturing biomedical devices such as implants that yield at least superior dimensional matching to the patient's body and hence should promote superior tissue and bone ingrowth as compared to conventional methods. In general, the smaller the gap between fragments or surfaces which are intended to heal to each other, the greater the likelihood of successful healing is believed to be. The implants of the present invention are anatomically accurate, thus providing an optimal fit with the patient's anatomy, which should promote healing. Furthermore, internal microarchitectures can be designed into the implant to promote, guide, or discourage ingrowth of bone or other tissue in specific places. The configuration of the architecture provides an environment beneficial to and optimized to cell ingrowth, and further can be designed to create a unique cell-surface interface that facilitates rapid and specific cell migration into the implant. This is possible due to specifically designed architecture as well as the ability to place drugs, gene fragments, comb polymers, and growth factors in specific locations within the implant. Such details are included in the machine instruction file as just described. Using the machine instruction file, the device is manufactured such as by three-dimensional printing. It is then inspected, sterilized if required, packaged, and delivered to the user.

Figure 2 is a diagram further showing steps of the method and illustrating the flow of data and certain decision points in the process in accordance with the present invention that more specifically illustrates the interaction of a central site. The central site receives data from remote sites, engages in some processing of that data and interaction with remote sites, and finally is involved in the manufacturing and shipping of parts to remote sites. At a central site 200, information is processed. Patient specifications 202, patient data 208 in the form of an MRI or CT scan, product

Figure 2 further shows a decision point as to whether or not to accept the design, approve the order, and initiate manufacture. At this point the multi-dimensional model file 212 resulting from the consultative process would be further translated into manufacturing instructions 214 as previously described, and the manufacturing instructions would in turn be used to manufacture custom biomedical device 216.

In addition to custom manufacturing a device, such as an implantable reconstructive, augmentative, rehabilitative or cosmetic device, from a patient's unique diagnostic data such as an MRI/CT scan, a customized best fit can be achieved. For example, patient-unique data can be transmitted to a remote site and then used to decide whether one of a number of standard designs is appropriate for the patient and which one is the best fit. Then, this standard design can be shipped directly from stock if available. Upon final agreement, the implant device would be retrieved from stock if it were in stock or could be manufactured to order, but with less specific labor and effort than is involved in a fully customized design. Depending on various factors such as price, timing, and the location in the body of the implant, customization can include either a best fit from standardized sizes or a one of a kind customized construction. The implant is then shipped to the doctor, and is implanted in the patient.

There are several differences between a completely customized implant and a best fit from stock implant. If an implant is a completely customized implant, it would have the best possible matching to a patient's own dimensions, as a result of being custom-manufactured, and presumably only one of them would be made. Presumably the multi-dimensional model and the resulting machine instructions would both be fairly complex. On the other hand, if it is decided that a fully customized implant is not necessary, there are two other possibilities. One is to supply an implant that is fully customized for another patient who closely resembles the current patient. The files would probably be similarly complex, but would not be correct to the same level of detail for the individual patient. Another way would be to design a multi-dimensional model that is a generic part, not derived from the specific data of any particular patient. Such a model would probably be less detailed, and more of these parts would probably be manufactured simultaneously at a lower manufacturing cost.

include accepting the input of patient specifications or the facilitation of imaging data such as an MRI/CT collection, initiating an initial proposal for the product design for the patient, a display of the multi-dimensional viewable models of the implants, management of the client feedback and commentary, and the maintenance of order status through delivery of the implant to the client. Thus, the secure web site 300 provides a central information exchange platform.

The patient data 310, including specific imaging data such as MRI/CT files, provide the basis for developing the customized implant. The client interaction 320 includes, *inter alia*, an initial patient profile, a review of the proposed product, comments and questions regarding the product, and an approval of the final order. Client interaction 320 can be via email, telephonically or through traditional mail routes. Client interaction 320 may be initiated through direct contact 322 or via a customer service 330 operation.

Customer service 330 serves to respond to inquiries regarding customized implants as well as match product designs to patient specifications and facilitate the ordering process. Customer service 330 also may provide electronic mail updates or alerts regarding the implant, may respond to client's queries via telephone, mail, or electronic mail, and may facilitate direct sales. An information system 340 provides control of implant data, inventory control, web management and billing.

The final product design 350 can be viewed on the secure web site 300 prior to manufacture and/or shipment, and files can be stored in the information system 340 for future reference. The secure web site 300 may also allow the client, for example, the oral or maxillofacial or other surgeon 360 to directly input specifications, requests, or parameters. The website can maintain a permanent record of the doctor's instructions in ordering the part, so as to function in much the same way as a prescription.

Yet another use of a secure central website could be as a facility for comparing data taken on a given patient at different times, even for the purpose of obtaining specific dimensional comparisons or changes. In taking a CT scan or a MRI scan, data is taken at a series of imaginary planes through a patient's body, with the

density might be able to be compared as an indicator, for example, of osteoporosis or other degenerative condition. Even local chemical composition, which is one of the strengths of MRI as a diagnostic technique, might be able to be compared or analyzed. Having all of this maintained on a central site, which may include specialized software, enables time-variation or progression to be studied which may include various stages in the progression of a degenerative disease, followed by design of a custom implant, followed by noting the appearance after implantation of the custom implant, followed by monitoring any changes in nearby bone after implantation, and even including indication of how much reabsorption has taken place in the case of a reabsorbable implant.

The computer facilities for converting an individual CT or MRI scan into a multi-dimensional model may not exist in every doctor's office, and similarly the computer facilities for comparing two different multi-dimensional models and detecting small dimensional changes are even less likely to exist in every doctor's office. Thus, the use of telecommunication such as the Internet provides the availability of such services to any location having appropriate communication facilities, regardless of geographic location.

In the case of an implantable drug delivery device, measuring the remaining size of the implantable drug delivery device could provide indication of how much drug has been delivered so far. In all cases, it would be desirable for communication with the central website or facility to be encrypted, as mentioned earlier and as is known in the art.

In some instances, the present invention may be used in a way which does not involve manufacturing to order, but rather involves selecting the best fit from a stock of already-manufactured components. While selection from stock does not provide all of the advantages of manufacturing completely customized parts to order, it nevertheless would provide some degree of customization that might be adequate for certain purposes. It also would be even faster than fully customized manufacture. In this sort of application, the central website would still receive radiographic data pertaining to a specific patient, and could assist in deciding which stock item should be

pattern of missing teeth, there may be more need for patient-specific manufacturing. In all of these cases, the use of a computer network to transmit patient-specific data is valuable, as is the use of the computer network to transmit patient-specific data such as visualizations back from the central location to the patient location.

The alveolar ridge is not by any means the only body part for which it may be useful to manufacture replacement pieces of possibly custom-shaped bone-like material possibly including internet transfer of data to provide exceptionally fast response and delivery time. Other possible body parts, shapes and devices include: cranial plugs; cheeks; mandible onlay; mandible extension; chin; nose; dental plug; external ear; gauze; orbital implants; orbital floor; orbital wall; orbital rims; orbital socket; croutons; wedges; plates; sheets; blocks; dowels; spine cage inserts; screws; tacks; custom pieces; cartilage; and soft tissue. These body parts are not meant as a complete or limiting list; others are also possible.

The term "croutons" refers to pieces of bone-like material that are used during surgery to fill voids in bone such as in piecing together complex fractures, thereby improving the likelihood of successful healing. They can be thought of as building blocks. Their shapes may be standard or custom or a hybrid and they may or may not include features for attachment. Wedges, sheets, plates, blocks and dowels are basic shapes similar to croutons. Orbital implants, rims, sockets, floors and walls are portions of the bone near the eye. Dental plugs are small pieces of bone substitute that could be placed at the site of a tooth extraction. A cranial plug would be used to fill a hole made in the skull for surgical purposes.

Some of these such as the external ear, and perhaps the nose, are non-rigid and would be made out of silicone or polyethylene, but again these are merely examples and other materials are also possible. For devices that are desired to be reabsorbable into the human body, examples of suitable materials are poly-L-lactic acid (PLLA) and poly-lactic-co-glycolic acid (PLGA), and similar polyesters. Suitable printing techniques take advantage of the solubility of these materials in chloroform.

Implantable drug delivery devices contain drugs and are made of a material that slowly degrades or dissolves in the body. Their function is to release drug

or other features of it may need to be customized for an individual patient. Other features of the design of a tissue scaffold which may affect its success in growing cells include composition of bulk materials and surfaces, deposition in specific places of surface-active agents which may either increase or decrease hydrophobicity, and deposition in specific places of bioactive materials, such as growth factors, and peptides. Use of the Internet for data transmission, possibly including patient-specific data, together with use of the rest of the techniques disclosed herein, can significantly speed up the availability time of custom-made or patient-specific tissue scaffolds.

In yet another embodiment, the present invention provides a new method of rapid design and manufacture of custom pharmaceuticals drugs such as Oral Dosage Forms (ODF) (pills); short-run applications to meet small, acute or emergency needs; via transmission of data over computer networks. In general the process would be what has already been described but simpler in that it would not require transmission of any detailed graphical data either from or to a doctor. Today most simple pills of common pharmaceuticals are of constant composition throughout and are made by pressing powder into a tablet shape.

Currently, there is a need for designing and manufacturing more complicated geometries of pills which would provide for delayed or gradual release of active pharmaceuticals, sequenced release of more than one pharmaceutical in a single pill, and in general somewhat arbitrary release profiles of multiple active pharmaceutical ingredients, all governed by the geometric design of the pill and the dissolution behavior of appropriate portions of the pill in bodily digestive fluids. For example, there may be a desire to combine multiple pharmaceutical compounds in a single oral dosage form as a way of improving patient compliance and accuracy in following instructions for self-administering medications. In general, in all sorts of medical treatments, noncompliance is a significant source of error or failure. Noncompliance can include patient unwillingness to take drugs, and also patient error in taking drugs. Compliance of patients would be increased by anything that decreases the number of pills that must be taken and/or decreases the number of times per day that pills must be taken. This may be useful, for example, in connection with treating either elderly or very young patients. For

and sending follow-up notices to either the physician or the patient. Billing can also be accomplished through such a web site, and interaction between the physician, patient, and insurance company can be facilitated. Product design updates, client feedback and follow-up notices to users can also be accomplished through such a web site, as can generation of statistical data. This method can include transmittal of information back to the prescriber at the time of prescribing, before finalizing of the order, or later. Such information can be maintained on a secure web site that is made available to appropriate categories of users, possibly including the use of encryption, or passwords.

In addition to implants, which would be defined as objects which are totally enclosed inside the body when they are put into use, the same techniques could also be used for manufacturing tooth substitutes or parts of teeth via communication of dimensional information to a distant site for manufacture. This could be done either in conjunction with reconstruction of maxillofacial bone products as already described, or separately. In the case of separately, it could be used to fabricate objects, *e.g.*, dental implants, dental onlays, dental inlays, dental crowns, dental caps, etc., *i.e.*, objects which are not at all enclosed by the skin of the body and which are visible when installed.

All of the above U.S. patents and applications are incorporated by reference. Aspects of these U.S. patents and applications can be employed with the teachings of the invention to provide further combinations.

From the foregoing it will be appreciated that, although specific embodiments of the invention have been described herein for purposes of illustration, various modifications may be made without deviating from the spirit and scope of the invention. Accordingly, the invention is not limited except as by the appended claims.

6. A method for manufacturing and selling individually fitted customized biomedical devices for a given recipient via a computer network, comprising:

capturing data in a computerized form;

converting the data to a multi-dimensional model;

modifying the multi-dimensional model to include an internal architecture,

converting the modified multi-dimensional model into machine instructions;

manufacturing a customized biomedical device from the machine instructions wherein the biomedical device is anatomically correct to the individual patient; and

shipping the biomedical device to the recipient for implantation.

7. The method of claim 6, further comprising transmitting the modified multi-dimensional model to the recipient for further modification prior to converting the model into machine instructions.

8. A method for manufacturing and selling customized medical devices via a computer network, comprising:

transmitting patient-specific data from a patient location to a secure web site via a computer network;

manufacturing the medical device based on the transmitted data;

delivery of the medical device; and

maintaining records of the patient-specific data.

9. The method of claim 8, further comprising generating follow-up notices based on the maintained records.

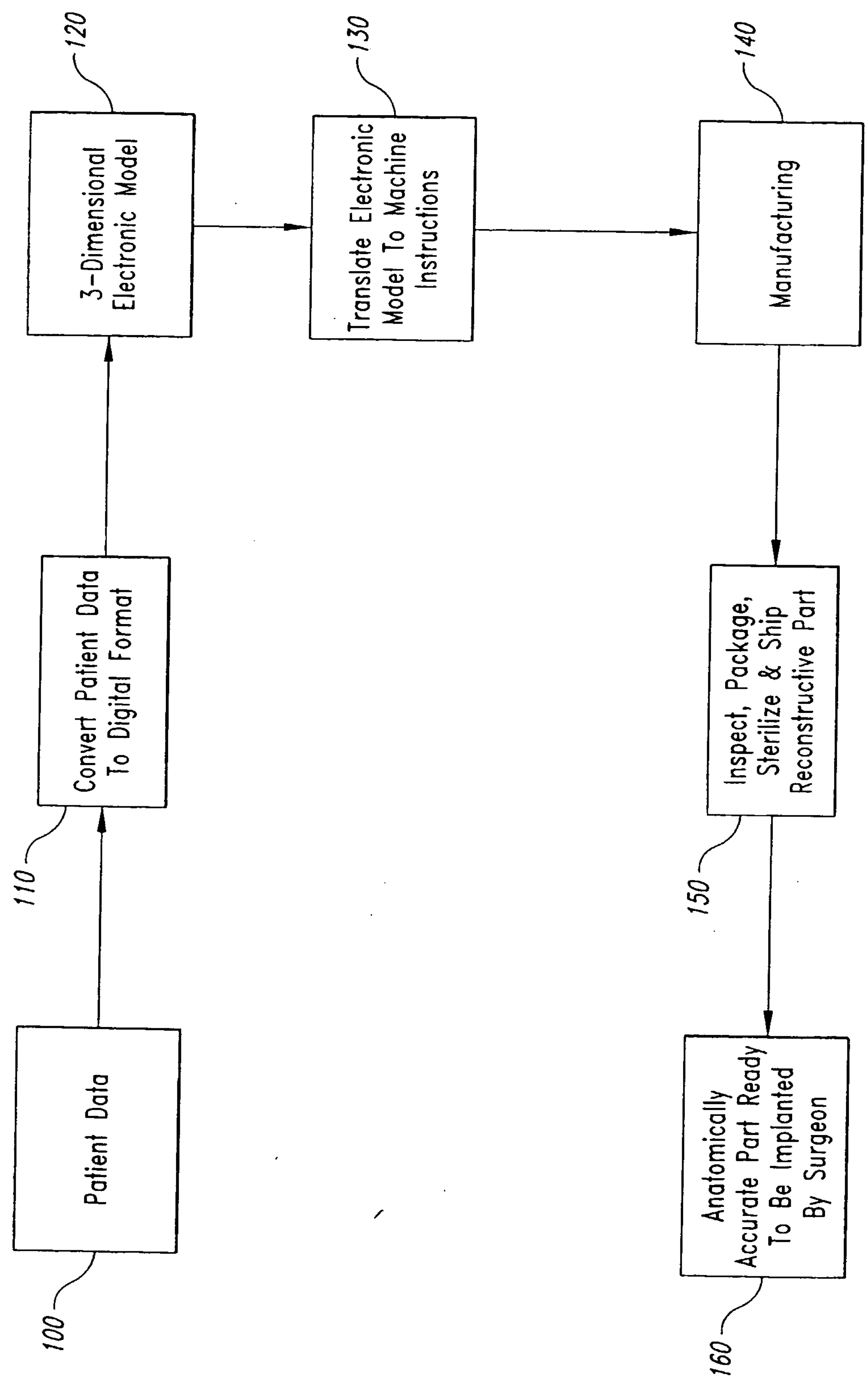
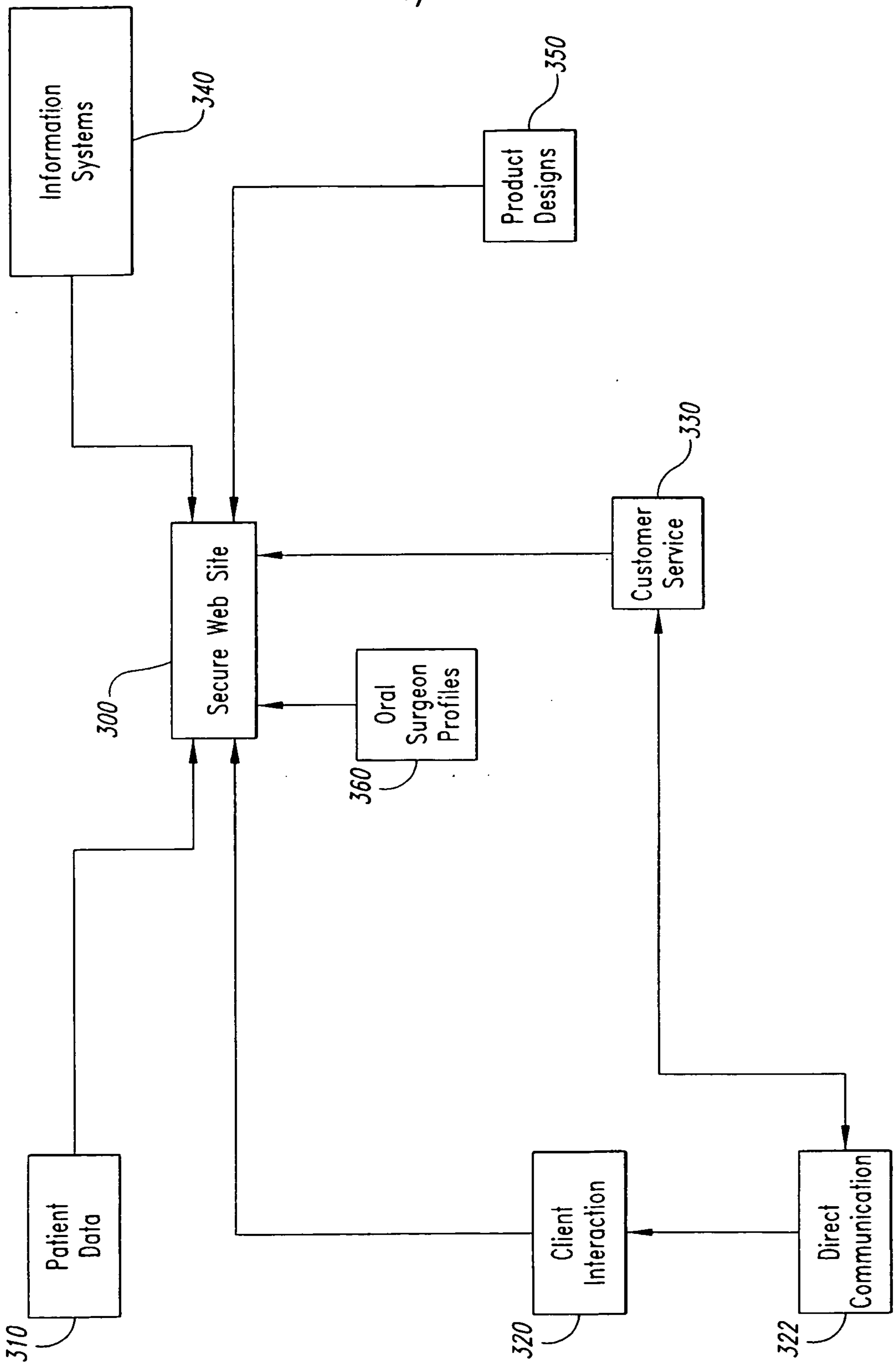

100
Patient Data
110
Convert Patient Data To Digital Format
120
3-Dimensional Electronic Model
130
Translate Electronic Model To Machine Instructions
140
Manufacturing
150
Inspect, Package, Sterilize & Ship Reconstructive Part
160
Anatomically Accurate Part Ready To Be Implanted By Surgeon

Fig. 1


Information Systems
340
Product Designs
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Secure Web Site
300
Oral Surgeon Profiles
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Customer Service
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Patient Data
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Client Interaction
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Direct Communication
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Fig. 3